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Remarks

Applicant appreciates the difference pointed out by the Examiner on page 2 of the Final Rejection of April 8, 2005:

The Examiner cannot differentiate between McGahn et al using separate silicone elastomer elements cement together with a silicone elastomer forming one-piece and applicant using a four layer envelope that is cured together forming one-piece.
[emphasis added]

Applicant has taken such a difference identified by the Patent Office and has placed such into each of the independent claims. The limitation placed into each of the independent claims in this case (claims 21, 26, 28, 33 and 36) is as follows:

f) with the envelope being made by a process comprising the steps of submerging a mandrel to pick up a first envelope layer over a first portion of the mandrel, then again submerging said mandrel to pick up a second envelope layer over a second portion of the mandrel, and then curing the envelope layers.

Basis for this limitation is found at least in original claim 18 filed December 1, 1999.

Such limitation, identified by the Patent Office, is patentably relevant at least for independent method claim 33.

The independent claims of the present case are similar to the independent claims of U.S. Patent No. 6,692,527, of which this case is a continuation. A Terminal Disclaimer To Obviate A Double Patenting Rejection Over A Prior Patent was filed in this case on January 16, 2005.

The side-to-side comparison set out below shows the relatively great extent of similarity between the independent claims of the two cases:

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Independent claims
of U.S. Patent No. 6,692,527

1. A breast implant for being implanted within a body, wherein the body includes front, rear, right and left sides, wherein the breast implant comprises:

a) an envelope having at least two sides, wherein the envelope is fillable with fluid to provide a three-dimensional shape to the envelope;

b) wherein one of the sides of the envelope comprises a relatively smooth surface;

c) wherein the other of the sides of the envelope comprises a relatively rough surface, wherein tissue growth by the body engages the relatively rough surface after the envelope has been implanted such that the envelope is restrained from rotating and such that the relatively smooth surface may be oriented as desired within the body;

d) wherein one of the sides of the envelope is thicker than the other of the sides of the envelope, wherein the thicker side of the envelope comprises the relatively rough surface, and wherein the thinner side of the envelope comprises said relatively smooth surface; and

e) wherein the envelope includes an opening through which a mandrel has been removed, wherein the envelope is sealed with a patch engaged over the opening and to the envelope, and wherein the envelope apart from said patch is one-piece.

Independent claims
of the present case, which claims
benefit of U.S. Patent No. 6,692,527

Claim 21. (currently amended) An implant for being implanted within a body, wherein the body includes front, rear, right and left sides, wherein the implant comprises:

a) an envelope having at least two sides, wherein the envelope is fillable with fluid to provide a three-dimensional shape to the envelope;

b) wherein one of the sides of the envelope comprises a relatively smooth surface;

c) wherein the other of the sides of the envelope comprises a relatively rough surface, wherein tissue growth by the body engages the relatively rough surface after the envelope has been implanted such that the envelope is restrained from rotating and such that the relatively smooth surface may be oriented as desired within the body;

d) wherein one of the sides of the envelope is thicker than the other of the sides of the envelope, wherein the thicker side of the envelope comprises the relatively rough surface, and wherein the thinner side of the envelope comprises said relatively smooth surface; and

e) wherein the envelope is sealable after being filled with said fluid, and wherein said thicker side is one-piece with said thinner side; and

f) with the envelope being made by a process comprising the steps of submerging a mandrel to pick up a first envelope layer over a first portion of the mandrel, then again submerging said mandrel to pick up a second envelope layer over a second portion of the mandrel, and then curing the envelope layers.

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6. A non-rotating anatomical-shaped breast implant for being implanted within a body, wherein the body includes front, rear, right and left sides, with the non-rotating anatomical-shaped breast implant comprising:

a) an envelope formed in the anatomical shape of a breast, wherein the envelope comprises front, rear, right and left sides;

b) wherein the envelope is fillable with fill material;

c) wherein the front side of the envelope comprises a relatively smooth surface;

d) wherein the rear side of the envelope comprises a relatively rough surface, wherein tissue growth by the body engages the relatively rough surface after the implant has been implanted such that the envelope is restrained from rotating and such that the front, rear, right and left sides of the envelope remain respectively oriented toward the front, rear, right and left sides of the body; and

e) wherein the envelope includes an opening through which a mandrel has been removed, wherein the envelope is sealed with a patch engaged over the opening and to the envelope, and wherein the envelope apart from said patch is one-piece.

Claim 26. (currently amended) A non-rotating implant for being implanted within a body, wherein the body includes front, rear, right and left sides, with the implant comprising:

a) an envelope, wherein the envelope comprises front, rear, right and left sides;

b) wherein the envelope is fillable with fluid fill material;

c) wherein the front side of the envelope comprises a relatively smooth surface;

d) wherein the rear side of the envelope comprises a relatively rough surface, wherein tissue growth by the body engages the relatively rough surface after the implant has been implanted such that the envelope is restrained from rotating and such that the front, rear, right and left sides of the envelope remain respectively oriented toward the front, rear, right and left sides of the body; and

e) wherein the envelope is sealable after being filled with said fluid fill material, and wherein said front side having said relatively smooth surface is one-piece with said rear side having said relatively rough surface; and

f) with the envelope being made by a process comprising the steps of submerging a mandrel to pick up a first envelope layer over a first portion of the mandrel, then again submerging said mandrel to pick up a second envelope layer over a second portion of the mandrel, and then curing the envelope layers.

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8. A breast implant comprising:

- a) an envelope having an anterior side, posterior side, superior pole, inferior pole and a nipple position, with the nipple position being on the anterior side near the inferior pole;
- b) wherein the anterior side has a first thickness;
- c) wherein the posterior side has a second thickness;
- d) wherein the first thickness of the anterior side is less than the second thickness of the posterior side; and
- e) wherein the envelope includes an opening through which a mandrel has been removed, wherein the envelope is sealed with a patch engaged over the opening and to the envelope, and wherein the envelope apart from said patch is one-piece.

Claim 28. (currently amended) An implant comprising:

- a) an envelope having an anterior side, posterior side, superior pole, and inferior pole;
- b) wherein the anterior side has a first thickness;
- c) wherein the posterior side has a second thickness;
- d) wherein the first thickness of the anterior side is less than the second thickness of the posterior side; and
- e) wherein the envelope is sealable after being filled with fluid, and wherein said anterior side is one-piece with said posterior side; and
- f) with the envelope being made by a process comprising the steps of submerging a mandrel to pick up a first envelope layer over a first portion of the mandrel, then again submerging said mandrel to pick up a second envelope layer over a second portion of the mandrel, and then curing the envelope layers.

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14. A method for minimizing rotation of a breast implant within a body, comprising the steps of:

a) selecting a breast implant having an envelope, wherein the envelope includes an opening through which a mandrel has been removed, wherein the envelope is sealed with a patch engaged over the opening and to the envelope, and wherein the envelope apart from said patch is one-piece, with the step of selecting a breast implant comprising the step of forming a relatively thin envelope side and a relatively thick envelope side with each other;

b) forming a relatively rough surface on an exterior portion of the relatively thick envelope side of the breast implant and forming a relatively smooth surface an exterior portion of the relatively thin envelope side of the breast implant;

c) implanting the breast implant within the body so as to orient the relatively smooth surface in a desired direction; then

d) permitting tissue growth to engage the relatively rough surface so as to anchor the breast implant in place, thereby minimizing rotation of the breast implant and holding the relatively smooth surface and relatively thin envelope side in the desired direction.

Claim 33. (currently amended) A method for minimizing rotation of an implant within a body, comprising the steps of:

a) selecting an implant having an envelope, wherein the envelope is sealable after being filled with fluid, with the step of selecting an implant comprising the step of forming a relatively thin envelope side and a relatively thick envelope side such that said relatively thin envelope side is one-piece with said relatively thick envelope side;

b) forming a relatively rough surface on an exterior portion of the relatively thick envelope side of the implant and forming a relatively smooth surface an exterior portion of the relatively thin envelope side of the implant;

c) implanting the implant within the body so as to orient the relatively smooth surface in a desired direction; then

d) permitting tissue growth to engage the relatively rough surface so as to anchor the implant in place, thereby minimizing rotation of the implant and holding the relatively smooth surface and relatively thin envelope side in the desired direction; and

f) with the envelope being made by a process comprising the steps of submerging a mandrel to pick up a first envelope layer over a first portion of the mandrel, then again submerging said mandrel to pick up a second envelope layer over a second portion of the mandrel, and then curing the envelope layers.

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17. A non-rotating breast implant for being implanted within a body, wherein the body includes front, rear, right and left sides, with the non-rotating breast implant comprising:

a) an envelope, wherein the envelope comprises front, rear, right and left sides;

b) wherein the envelope is fillable with fill material;

c) wherein the front side of the envelope comprises a relatively smooth surface;

d) wherein the rear side of the envelope comprises a relatively rough surface, wherein tissue growth by the body engages the relatively rough surface after the implant has been implanted such that the envelope is restrained from rotating and such that the front, rear, right and left sides of the envelope remain respectively oriented toward the front, rear, right and left sides of the body; and

e) wherein the envelope includes an opening through which a mandrel has been removed, wherein the envelope is sealed with a patch engaged over the opening and to the envelope, and wherein the envelope apart from said patch is one-piece.

Claim 36. (currently amended) A non-rotating implant for being implanted within a body, wherein the body includes front, rear, right and left sides, with the non-rotating implant comprising:

a) an envelope, wherein the envelope comprises front, rear, right and left sides;

b) wherein the envelope is fillable with fluid fill material;

c) wherein the front side of the envelope comprises a relatively smooth surface;

d) wherein the rear side of the envelope comprises a relatively rough surface, wherein tissue growth by the body engages the relatively rough surface after the implant has been implanted such that the envelope is restrained from rotating and such that the front, rear, right and left sides of the envelope remain respectively oriented toward the front, rear, right and left sides of the body; and

e) wherein the envelope is sealable after being filled with said fluid fill material, and wherein said front side having said relatively smooth surface is one-piece with said rear side having said relatively rough surface, and

f) with the envelope being made by a process comprising the steps of submerging a mandrel to pick up a first envelope layer over a first portion of the mandrel, then again submerging said mandrel to pick up a second envelope layer over a second portion of the mandrel, and then curing the envelope layers.

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As a review of the above claims will show, the scope of the claims, prior to the present amendment, are very similar. The major difference is that the claims of the patent have a "breast" limitation.

For the record, the rejections of the Office Action of April 8, 2005 are hereby respectfully traversed. The rejections are based on 1) McGhan (section 102, all claims), 2) Prescott (section 102, all claims), 3) Baker (section 102, claims 28, 30, 32, 39 and 44) (claim 32 has been canceled), and 4) McGhan et al. or Prescott (section 103, claims 42-46).

The references, individually or in combination, do not teach a first side (with front, back, relatively thin, relatively thick, relatively rough, or relatively smooth side claim requirements depending upon the claim presented) being one-piece with a second side (with front, back, relatively thin, relatively thick, relatively rough, or relatively smooth side claim requirements depending upon the claim presented).

The Amendment and Remarks of January 16, 2005 is hereby incorporated by reference in its entirety. A review of such will show that:

- The McGhan et al. reference teaches five pieces, not one piece. The present claims require a one-piece envelope.
- The Prescott reference does not teach an implant that can be filled with fluid. The present claims require an envelope that is fillable with fluid to provide a three dimensional shape.
- The Baker reference is not enabling because it does not teach how the shell component and the reinforcement member can be formed as an integral unit.

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As to the independent product claims 21, 26, 28, and 36

The product claims positively recite a new product.

Applicant's basis for such is as follows:

- Applicant patented the product claims of U.S. Patent No. 6,692,527.
- The Patent Office has requested a Terminal Disclaimer in this case.
- Applicant has filed the requested Terminal Disclaimer in this case.
- Applicant specifically pointed out product limitations as to product independent claims 21, 26, 28 and 36 in applicant's Amendment and Remarks of January 16, 2005, which Amendment and Remarks are hereby incorporated by reference.

As to independent method claim 33

Independent method claim 33 positively recites a new method.

Applicant's basis for such is as follows:

- Applicant patented the corresponding method claim 14 of U.S. Patent No. 6,692,527.
- The Patent Office has requested a Terminal Disclaimer in this case.
- Applicant has filed the requested Terminal Disclaimer in this case.
- The Patent Office has identified a difference between the methods of McGhan et al. and applicant, and this difference is now claimed. Please see the first paragraph of page 9 of this Preliminary Amendment.

Summary

The Examiner is respectfully invited to make contact with

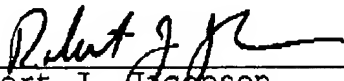
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the undersigned by telephone if such would advance prosecution of this case.

Respectfully submitted,

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